UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

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SYED MAHMOOD, M.D.

***Plaintiff*,**

Case No.: 7:20-CV-2550

-v-

PROGENICS PHARMACEUTICALS, INC.,

Defendant.

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COMPLAINT AND DEMAND FOR JURY TRIAL

Plaintiff Syed Mahmood, M.D., ("Plaintiff" or "Dr. Mahmood"), by his attorneys, RCTobinLaw, PLLC, for his Complaint alleges as follows based upon personal knowledge as to his own actions and on information and belief as to all other matters:

THE NATURE OF THE ACTION

1. Plaintiff brings this action against Defendant Progenics Pharmaceuticals, Inc. ("Defendant" or "Progenics") for violations of Section 806 of the Sarbanes-Oxley Act, 18 U.S.C. § 1514A, *et seq*.

PRELIMINARY STATEMENT

2. This case concerns a cancer researcher – Dr. Syed Mahmood – who blew the whistle on his employer, a pharmaceutical and medical technology development company. As an unjust result of his whistleblowing, Dr. Mahmood was retaliated against by

his employer, and was wrongfully fired.

3. On at least three occasions, beginning in early January 2019, and until his employment was terminated on April 18, 2019, Dr. Mahmood warned Progenics' senior management about serious, ongoing violations (collectively, the "Violations") by Progenics executives of Company Compliance Program (the "Progenics Compliance Program") and the United States Office of the Inspector General ("O.I.G.") Compliance Program Guidance for Pharmaceutical Manufacturers (the "O.I.G. Guidelines").

4. The Violations related to the roll-out of an important, eagerly anticipated new Progenics cancer drug, AZEDRA®.

5. The Violations included: improper promotion of unapproved, off-label sales of AZEDRA® by **(a) failing to restrict** prohibited **interactions between the** Progenics' **commercial** department **("Commercial**"), **which is responsible for marketing and sales, and medical affairs department ("Medical Affairs")** including planning off-label sales training; **(b) failing to ensure** that **Commercial undertakes tactical implementation of Medical Affairs activities**, including designing and setting up Medical Affairs booths, and providing research updates of and promoting "off-label" uses of AZEDRA® and other products to at Medical conferences; and **(c) failing to ensure that health care providers ("HCPs")** were **provided with unsolicited confidential off-label information about AZEDRA® unless and until those** HCPs **had executed confidentiality and reporting of transfer of value agreements** as an inducement to prescribe or use Progenics products.

6. As an experienced pharmaceutical professional and a member of the Progenics Compliance Committee, Dr. Mahmood knew that the Violations were likely to lead to artificial inflation of the sales results for Progenics' cancer drug, AZEDRA®.

7. Dr. Mahmood knew that these inflated sales results would falsely suggest that Progenics was successfully marketing AZEDRA® and encourage investors to believe that Progenics' current management was successfully marketing AZEDRA®. The Violations were therefore likely to result in violations of various provisions of federal law relating to fraud, including wire fraud, bank fraud, and securities fraud.

8. In fact, as Dr. Mahmood knew, Progenics had failed to market AZEDRA® successfully.

9. Further, Progenics' management engaged in a months-long cover-up: to conceal Progenics' failure to market AZEDRA® for FDA-approved uses from Progenics' shareholders, Progenics aggressively marketed AZEDRA® for ***off-label*** uses for which approval by the Federal Drug Administration ("FDA") had not even been requested.

10. Because sales of AZEDRA® for off-label purposes were indistinguishable on Progenics' balance sheet from sales for FDA-approved purposes, Progenics' scheme concealed from its investors the fact that Progenics' attempts to market AZEDRA® for on-label purposes had failed.

11. Progenics engaged in this scheme to deceive investors as to the value of its highly-touted, FDA-approved new cancer drug both to encourage investment in the Company and to defeat an attempt by a group of highly vocal shareholders to replace the Company's managers and certain members of its Board of Directors.

12. Led by Velan Capital, L.P., beginning in the fourth quarter of 2018, that group of dissenting investors (collectively, "Velan Capital") engaged in a year-long dispute with management, alleging, *inter alia,* that Progenics' senior management had botched, and had not been transparent with respect to, the roll-out of AZEDRA®.

13. Progenics' dispute with Velan Capital culminated in a proxy fight that enabled Velan Capital, by the fall of 2019, to replace Progenics' Chief Executive Officer Mark Baker and five of seven members of the Board of Directors.

14. In diligently fulfilling his responsibilities to Progenics and its shareholders by blowing the whistle on the Violations, Dr. Mahmood's actions threatened to derail Progenics' illegal scheme.

15. Because he sought to prevent a fraud perpetrated upon the Progenics' shareholders, on April 18, 2019, Defendant retaliated against Dr. Mahmood by terminating his employment, thereby violating Section 806 of the Sarbanes-Oxley Act ("SOX"), which prohibits retaliation against whistleblowers.

16. Because of the Defendants' illegal actions, Dr. Mahmood has suffered substantial damages, including loss of income, reputational damage, and other substantial losses, and has brought this action under to obtain compensation for his injuries.

JURISDICTION

17. This Court has subject matter jurisdiction over Plaintiff's claim pursuant to 28 U.S.C. § 1331 and 15 U.S.C. § 78u-6(h)(l)(B)(i).

18. **Plaintiff has exhausted the administrative remedies available to him under the Sarbanes-Oxley Act in that, on or about July 8, 2019, he filed a Sarbanes-Oxley Complaint with the United States Department of Labor in accordance with 18 U.S.C. § 1514A(b)(l)(B). The Secretary of Labor did not issue a final decision within 180 days of that filing.**

VENUE

19. Venue is proper in this District under 28 U.S.C. § 1391(b)(2) because a substantial part of the events or omissions giving rise to Plaintiff's occurred within the

Southern District of New York. Venue is also proper in this District under 28 U.S.C. § 1391(b)(1) because Defendant resides in this district and all defendants are residents of the State of New York.

THE PARTIES

20. Plaintiff is a physician certified by the American Board of Nuclear Medicine with specific experience in general nuclear medicine, positron emission tomography (PET) and therapeutic applications of radionuclides.

21. Plaintiff resides at 18 Dorann Road, Purchase New York, 10577.

22. Defendant Progenics is a Delaware corporation and a "company" within the meaning of 18 U.S.C. § 1514A. Its principal place of business is at One World Trade Center, 47th Floor, Suite J, New York, New York 10007. Progenics transacts business within the State of New York.

23. Defendant is an oncology company focused on the development and commercialization of innovative targeted medicines and artificial intelligence to find, fight and follow cancer.

24. On October 1, 2019, Defendant entered into an agreement with Lantheus Holdings Inc. ("Lantheus"), a Delaware corporation, pursuant to which Lantheus will acquire Progenics in an all-stock transaction (the "Acquisition").

25. The Acquisition is currently scheduled to close in the second quarter of 2020, and as soon as April 2020.

FACTUAL BACKGROUND

I. Dr. Mahmood's Employment by Progenics

26. A graduate of the George Washington University School of Medicine and Health Sciences, Dr. Mahmood completed his residency in Nuclear Medicine and Nuclear

Oncology at the Memorial Sloan Kettering Cancer Center ("MSKCC"), where he was chief resident.

27. As MSKCC chief resident, Dr. Mahmood supervised and participated in nuclear medicine studies and therapies, evaluated patients for Nuclear Medicine therapies, and was responsible for the recruitment, selection and retention of residents.

28. While a medical student, Dr. Mahmood was the recipient of numerous awards and scholarships, including the Ammerman Scholarship Award, Kaplan Tuition Scholarship Award and American Pediatric Society Stipend for Gifted Medical Students. He was a member of the William S. Beaumont Research Honor Society.

29. Prior to his employment by Progenics, from 2013 to 2017 Dr. Mahmood served as the Lead for U.S. Clinical Development and Medical Affairs for Novartis, where, *inter alia*, he developed research strategies for Novartis cancer drugs.

30. On February 25, 2019, Dr. Mahmood received a favorable performance review from his supervisor, Dr. Vivien Wong.

31. Dr. Mahmood was awarded the full individual performance-based incentive pay award (annual bonus) for which he was eligible, and a merit-based salary increase for 2019.

32. Dr. Mahmood's performance review included the following statement by Dr. Wong: "despite the shortage of resources, Syed covered the broad scope of MA relating to AZEDRA®— primarily on his own with some vendor support, and all the while maintaining a positive demeanor. Such flexibility and professionalism should be recognized and commended."

33. Throughout his employment by Progenics, from September 5, 2017 through April 18, 2019, Dr. Mahmood reported directly to Dr. Wong, who at all

relevant times served as Progenics' Executive Vice President of Development.

34. In all Progenics Human Resource and e-mail systems that were visible to Dr. Mahmood during the period of his employment, Dr. Wong was listed as his supervisor at all relevant times.

35. Throughout his employment, Dr. Mahmood performed his duties and responsibilities for Progenics in a highly professional manner. His proficiency in his job was reflected by, among other things, his performance reviews and the consistent increases in his compensation.

36. Dr. Mahmood's responsibilities at Progenics included membership serving as a member of the Compliance Committee.

37. As a member of the Compliance Committee, Dr. Mahmood's duties included ensuring that Medical Affairs and other Progenics departments, including Commercial, complied with the Progenics Compliance Program and O.I.G. Guidelines.

38. As a member of the Compliance Committee, Dr. Mahmood was required to report to Progenics' senior management any violations by Progenics employees of the Progenics Compliance Program, O.I.G. Guidelines, or any other policies, guidelines, regulations or laws that pertained to pharmaceutical or publicly owned companies.

II. Progenics' Compliance Program and the O.I.G. Guidelines

39. The Progenics' Compliance Program cites the O.I.G. Guidelines, stating, in relevant part:

> Progenics Pharmaceuticals, Inc. (Progenics) is committed to conducting its business in compliance with all applicable laws, rules, and regulations and the highest standards of ethical conduct. To this end, we have established and will maintain a Comprehensive Compliance Program ("Compliance Program") in accordance with the *OIG Compliance Program Guidance for Pharmaceutical Manufacturers* [defined term omitted] published by the Office of Inspector General, U.S. Department of Health and Human Services.

(*Emphasis added*).

40. As of March 5, 2020, the Progenics Compliance Program was summarized on the Company's web site, which described among other things the Company's policy governing the participation of health care providers in meetings and conferences. The summary was accessible at https://www.progenics.com/about-us/compliance/ on March 5, 2020.

41. The Progenics Compliance Program states that the purpose of the Program is, among other things, to "prevent, detect, and remediate violations of laws, rules and regulations, as well as Progenics policies and procedures."

42. In addition, in the "Statement of Purpose" in Section 1, *Progenics' Policy on Reporting and Investigating Complaints* affirms the Company's obligation to comply with applicable legal and regulatory requirements, including "securities compliance and other matters pertaining to fraud against shareholders."

43. As a member of the Compliance Committee, Dr. Mahmood Syed knew from Progenics' policies that violations of the Progenics Compliance Program and O.I.G. Guidelines, including the Violations, were likely to result in violations of various provisions of federal law relating to fraud, including wire fraud, bank fraud, and securities fraud.

44. In furtherance of its stated objectives, the Progenics Compliance Program requires that, before any health care provider can be admitted to a company meeting or conference, provided with confidential information about a Progenics pharmaceutical product or compensated in cash or equivalent value for services provided by the health care provider to Progenics, a Confidentiality Agreement must be prepared by Progenics and signed by the health care provider.

45. The Progenics Compliance Program also states, among other things, that it is Progenics' policy not to "provide anything of value to healthcare professionals/organizations in a manner or on conditions that would interfere with the independence of their treatment decisions or as an inducement to prescribe or use Progenics products." (*Progenics Compliance Program* at 1.0.)

46. The purposes of the confidentiality and compensation provisions included, *inter alia*, to ensure that HCPs are not induced by the Company with financial or other benefits – *i.e.*, "perks."

47. An additional purpose of the confidentiality and compensation contract is to ensure that and Progenics' confidential information is not exploited or misused for either Progenics' or the HCPs financial benefit.

48. Such confidential information includes about "off-label" uses of pharmaceuticals.

49. Further, in Section 3, the Progenics Compliance Program sets out rules for the Commercial Department's promotion and marketing of Progenics products. (*See Progenics Compliance Program* at 3.1.1 – 3.1.3.)

50. The rules set forth in Section 3 of the Progenics Compliance Program apply to the creation and distribution of promotional materials describing "off-label" or unapproved uses of Progenics products. Those rules also restrict discussions, and certain other interactions, between Commercial and Medical Affairs, and marketing "off-label" uses of Progenics products.

51. For example, Sections 3.1.1-3.1.3 state that, before promotional materials are distributed, they must be authorized "through the Medical, Legal and Regulatory

Affairs Review Committee Standard Operating Procedure" and comply with FDA regulations.

52. Sections 3.1.1-3.1.3 specifically provide that Progenics employees and contractors "shall not promote any 'off-label' or unapproved use of Progenics product in any promotional materials and/or informational presentations" or "solicit or prompt 'off-label' questions." (*See id.*)

53. Sections 3.1.1-3.1.3 further require that vendor and HCP questions about off-label uses of Progenics' drugs should be referred directly to and answered by Medical Affairs – not Commercial.

54. The rules in Section 3 are intended, at a minimum, to avoid premature sales in off-label or as yet to be approved indications and inflated bottom-lines such as Progenics sought to achieve through disclosing unsolicited "off-label" uses with health care providers without a confidentiality agreement, by not reporting transfer of value as an inducement to prescribe or use Progenics products, prohibited collaboration between its Commercial and Medical Affairs Departments including planning off-label sales training, and Commercial promoting "off-label" uses of Progenics products at Medical conferences through designing and setting up Medical Affairs booths – upon which Dr. Mahmood blew the whistle.

III. Progenics' Failure to Market AZEDRA® Effectively.

55. On February 8, 2019, Dr. Mahmood had the first of three conversations (the "February Disclosure") with Aseem Anand, Ph.D., Progenics Vice-President of Digital Technology and a member of the Progenics' Management Team.

56. Dr. Anand told Dr. Mahmood in that conversation that, contrary to what Progenics was telling investors, there were no potential patients in the "pipeline" for on-label uses of AZEDRA®.

57. Dr. Anand told Dr. Mahmood that, as of February 8, 2019, there

had not been even a single order by health care professionals for AZEDRA®.

58. Because Dr. Anand was a member of the Management Team, Dr. Mahmood reasonably believed that Dr. Anand had first-hand knowledge of the Company's marketing efforts, including its effort to market AZEDRA® for on-label uses.

59. At the time of the February Disclosure, Dr. Mahmood had already become concerned, and had reported to Progenics' management, the first of three Violations of Progenics Compliance Policy.

IV. Dr. Mahmood Blows the Whistle

60. On January 2, 2019, Progenics announced the appointment of Dr. Asha Das ("Dr. Das") as Progenics' Chief Medical Officer.

61. Progenics management informed Dr. Mahmood and other Progenics professionals that Dr. Das' first assignment would be to plan and manage the roll-out of AZEDRA®.

62. In early January 2019, Dr. Das told Dr. Mahmood that she planned to schedule an Advisory Board meeting ("February Advisory Board Meeting") to discuss the potential uses of AZEDRA®, including the drug's off-label applications.

63. Advisory Board members include physicians – HCPs - who are not Progenics employees but have entered into contracts with Progenics to attend an Advisory Board meeting and provide advice about a specific topic or Progenics product.

64. Dr. Das told Dr. Mahmood that the February Advisory Board Meeting would take place in three weeks.

65. Dr. Mahmood warned Dr. Das that three weeks was not a sufficient period to allow Progenics to comply with the Progenics Compliance Program and O.I.G. Guidelines.

66. Dr. Mahmood told Dr. Das that the necessary paperwork prescribed in the Progenics Compliance Program, including signed Confidentiality Agreements, could not be prepared and completed in three weeks' time.

67. Nonetheless, on January 17, 2019, Dr. Mahmood was told by a MSKCC physician, Dr. Pandit-Taskar, that Dr. Das and Jessica Jenson, Progenics' Senior Vice President of Clinical Development, had finalized a list of health care providers to attend the February Advisory Board Meeting to discuss off-label uses of AZEDRA®.

68. Further, in mid-February 2019, approximately a week after the February Disclosure by Dr. Anand, Dr. Pandit-Taskar told Dr. Mahmood that she and another MSKCC physician had been invited to attend an Advisory Board meeting on February 21 and/or 23, 2019.

69. Dr. Pandit-Tasker also told Dr. Mahmood that confidentiality agreements limiting the doctors' use of any information acquired at the meeting had not been completed.

70. Dr. Mahmood knew that the Company intended to pay for private transportation for Dr. Pandit-Taskar and her colleague to and from the Advisory Board meeting, meals while in attendance, and to pay both physicians for their attendance.

71. Dr. Mahmood was aware that, without signed Confidentiality Agreements in place, the HCPs that attended the February Advisory Board Meeting would be able to use confidential information about AZEDRA® for any purpose, including prescribing it for off-label treatment.

72. Dr. Mahmood also was aware that sales of AZEDRA® for unapproved off-label uses would inflate sales reports for that drug, including in Progenics' upcoming federal securities filings.

73. Such misleading reports and filings, Dr. Mahmood reasonably believed, would violate federal law relating to fraud, including wire fraud, bank fraud, and securities fraud and would constitute fraud against shareholders prohibited under 18 U.S.C. § 1341, 17 C.F.R. § 240.10b-5, and Sarbanes Oxley § 1541A.

74. In a face-to-face meeting in mid-February, on the same day that he spoke to Dr. Pandit-Taskar, Dr. Mahmood told Dr. Das that, to avoid violations of the Progenics Compliance Program and O.I.G. Guidelines and prevent federal securities laws violations, Dr. Pandit-Taskar and Dr. Modak could not attend the Advisory Board meeting unless Confidentiality Agreements were executed.

75. **Dr. Das responded by advising Dr. Mahmood to "look the other way."**

76. **Dr. Das also told Dr. Mahmood that that the meeting would go forward and that, with or without contracts the doctors could attend.**

77. **Further, on February 21 and/or 23, the day prior to the meeting, Dr. Das reiterated to Dr. Mahmood that she would "not turn the doctors away if they showed up at Progenics."**

78. E-mail exchanges that took place after the February Advisory Meeting among Dr. Das's assistant Lucia Alessi and Progenics' Compliance Officer, Brian Dahl, confirmed Dr. Mahmood's belief that required protocols were not completed prior to the meeting.

V. Telephone Conference between Medical Affairs and Commercial: The Whistle Blows Again

79. From March 8, 2019 through March 31, 2019, Dr. Mahmood took a three-week vacation in Pakistan, preapproved by his supervisor, Dr. Wong.

80. On March 8, while he was on his way to Pakistan, Dr. Mahmood

received a series of text messages from Dr. Carlton Anderson ("Dr. Anderson"), his direct report. Dr. Anderson told Dr. Mahmood that Dr. Das, Progenics' Chief Medical Officer; and Bryce Tenbarge, Progenics' Senior Vice President of Commercial were engaging in an inappropriate exchange of tactical information and discussions about the off-label marketing of AZEDRA®, a violation of the Progenics Compliance Program and O.I.G. Guidelines.

81. On March 8, Dr. Anderson told Dr. Mahmood that, in a conference call scheduled for March 12 or 13 ("Medical/Commercial Conference Call"), Dr. Das planned to share confidential medical research about AZEDRA®'s off-label uses with the entire Progenics sales team.

82. In a follow-up text to Dr. Mahmood, Dr. Anderson stated that Dr. Das was behaving "as if she were the Chief Commercial officer, not the Chief Medical Officer."

83. At that time, Progenics had not applied to the FDA for approval of these as yet off-label uses of AZEDRA®.

84. Progenics did not plan to meet with the FDA to discuss approval of off-label uses of AZEDRA® until late in May 2019.

85. Based on his knowledge and understanding of the rules and purposes of the Progenics Compliance Program and O.I.G. Guidelines, Dr. Mahmood reasonably believed that, to avoid violations of federal law relating to fraud, including wire fraud, bank fraud, and securities fraud, including 18 U.S.C. § 1341 and 17 C.F.R. § 240.10b-5, a meaningful separation of Medical Affairs and Commercial organizations must be maintained, interactions between commercial personnel and MSLs be appropriately managed, and no information regarding AZEDRA®'s off-label uses could

be shared by Dr. Das with the sales team.

86. Dr. Mahmood knew that premature collaboration between the Medical Affairs and Commercial departments was intended to promote, and was likely to lead to, off-label sales of AZEDRA®.

87. Those sales would be reported to shareholders and potential investors, including the investors who were aligned with, or were being solicited by, Velan Capital.

88. Dr. Mahmood reasonably believed that, because they would not know that the profits that Progenics reported included profits from unapproved, off-label sales, investors would be misled into believing that the reported profits reflected approved, on-label sales of AZEDRA®.

89. Dr. Mahmood reasonably believed that the misleading sales reports would constitute fraud against shareholders within the meaning of U.S.C. § 1341 and 17 C.F.R. § 240.10b-5 and would violate additional provisions of federal law relating to fraud, including wire fraud, bank fraud, and securities fraud.

90. Acting on his concerns, Dr. Mahmood instructed Dr. Anderson to instruct the Progenics Compliance Officer to join the Medical/Commercial Conference Call.

91. Upon information and belief, acting on Dr. Mahmood's instructions, Dr. Anderson reached out to Brian Dahl, the Progenics Compliance Officer, voicing his concerns about the Medical/Commercial Conference Call.

92. Upon information and belief, Mr. Dahl participated for compliance purposes in the Medical/Commercial Conference Call.

93. Upon information and belief, the AZEDRA®

Medical/Commercial Conference Call took place on or about March 12, 2019. Participants in the call included Mr. Dahl, Dr. Das, Mr. Tenbarge and the Progenics' sales team.

VI. Continued Collaboration Between Medical Affairs and Commercial; Dr. Mahmood Blows the Whistle a Third Time

94. **On April 8, 2019, Dr. Mahmood was told by Dr. Anand (the "April Disclosures") that there were still no orders for AZEDRA® from health care providers, and that no patients were receiving the drug.**

95. On April 17, 2019, during a teleconference (the "April 17 teleconference") among Progenics' Senior Director of Sales and Marketing Gary Lunger, Mr. Tenbarge and Dr. Anderson, Dr. Mahmood learned that additional interactions between Medical Affairs and Commercial were in progress.

96. During the April 17 teleconference, Dr. Mahmood learned that Commercial had agreed to a scope of work, negotiated and signed a proposal with, and paid, IMPACT, a marketing vendor, to design and set-up Medical Affairs (and Commercial) booths and provide other services to Progenics during two medical conferences, ASCO 2019 and SNMMI 2019 ("June Medical Conferences"), scheduled to take place in June 2019.

97. Following the Progenics Compliance Program there was inadequate separate of Commercial and Medical Affairs at the June Medical Conferences, where Commercial had now undertaken tactical implementation of Medical Affairs activities, including providing research updates of as yet unapproved uses of AZEDRA® and other products to conference participants.

98. Following the rules set out in the Progenics' Compliance Program, Commercial could only design the Commercial booth for Progenics' approved products, but could not design the Medical booth in order to promote those products. For example,

Commercial could not acquire and disclose research and findings about products or promote uses that the FDA had not approved.

99. Dr. Mahmood believed that, in violation of the Progenics Compliance Program and O.I.G. Guidelines, Commercial had taken over the Medical Affairs booth under the flag of Commercial to aggressively market the as-yet-unapproved, off-label uses of AZEDRA®.

100. Dr. Mahmood reasonably believed that the profits resulting from those off-label sales would mislead shareholders into believing that AZEDRA® had been successfully marketed for on-label purposes.

101. Based on (a) the February and April Disclosures by Dr. Anand; (b) Dr. Mahmood's unsuccessful effort to persuade Dr. Das to obtain signed Confidentiality Agreements; (c) the initial agenda, disrupted by Dr. Mahmood's intervention, planned for the Medical/Commercial Conference Call; and now (d) the hi-jacking by Commercial of the June Medical Conferences, Dr. Mahmood understood that Progenics intended to cover up its failure to successfully market AZEDRA® by attempting to increase off-label sales.

102. Because the failure to sell AZEDRA® on-label was not public, and the off-label sales would be incorporated into a single AZEDRA® sales report, Dr. Mahmood believed that Progenics' scheme would mislead shareholders and potential investors into believing that Progenics had successfully commercialized AZEDRA®.

103. Dr. Mahmood recognized that Progenics' misrepresentations and omissions regarding the on-label sales of AZEDRA®, would violate federal law relating to fraud, including wire fraud, bank fraud, and securities fraud, including 18 U.S.C.A. § 1341, and 17 C.F.R. § 240.10b-5.

104. Immediately after the April 17 teleconference, Dr. Mahmood drafted an e-mail memorandum addressed to Dr. Das, stating his concern that the interactions between Medical Affairs and Commercial with respect to planning the June Medical Conference violated the Progenics Compliance Program and O.I.G. Guidelines.

105. In his email to Dr. Das, Dr. Mahmood warned that, to comply with the Progenics Compliance Program and O.I.G. Guidelines, Commercial should not be planning and/or implementing Medical Affairs activities.

106. **Dr. Mahmood wrote: "Please note that I am concerned that Commercial is suggesting making a determination of tactical activities for Medical Affairs."**

107. Dr. Das did not reply to Dr. Mahmood's warning.

108. The following morning, April 18, 2019, Dr. Das asked Dr. Mahmood to come to a meeting room for a "catch-up" meeting.

109. At that meeting, Dr. Das told Dr. Mahmood his performance "needed to be improved" and informed him that his employment by Progenics was terminated, effective immediately. Dr. Mahmood was terminated a mere six weeks after receiving a favorable performance review, three weeks during which period he was out-of-the-country to celebrate his marriage.

110. Progenics terminated Dr. Mahmood's employment in the midst a dispute, initiated in the fourth quarter of 2018, with the Velan Capital group of investors.

VII. Subsequent Events Confirm Progenics' Illegal Scheme

111. From May through July 2019, Velan Capital embarked on a proxy fight that successfully effected significant change in control of the company and replacement of certain members of the Board of Directors.

112. Key issues in Velan Capital's year-long dispute with Progenics management are stated in a letter from Velan Capital to shareholders dated May 6, 2019 (the "May 6 Letter to Shareholders"), **less than three weeks after Progenics' termination of Dr. Mahmood's employment.** In the May 6 Letter to Shareholders, Velan Capital called for changes in Progenics Board of Directors and Managers.

113. In the May 6 Letter to Shareholders, Velan Capital complained of Progenics' botched management of, and a lack of shareholder transparency regarding, the roll-out of AZEDRA®. Velan Capital identified these concerns as reasons for challenging Progenics' management and Board membership.

114. In November 2019, the Velan Capital proxy fight resulted, by November 2019, in the removal of Progenics CEO Mark Baker, removal of four members of the Board of Directors, and election by stockholders of five new independent directors.

https://www.businesswire.com/news/home/20191108005562/en/Velan-Receives-Requisite-Number-Written-Consents-Reconstitute

https://www.globenewswire.com/news-release/2019/07/12/1882012/0/en/Progenics-Announces-Preliminary-Voting-Results-of-Annual-Meeting-of-Shareholders.html

115. A full account of the proxy dispute can be accessed in SEC filings at SEC.gov. https://www.sec.gov/cgi-bin/browse-edgar?company=progenics&owner=exclude&action=getcompany).

116. On May 9, 2019, three days after the May 6 Letter to Shareholders, Progenics issued a press release (the "May 9 Press Release") and filed a 10Q with the SEC, reporting its first quarter financial results.

117. **On May 24, 2019, the Dr. Anand informed Dr. Mahmood that, in fact, there had been no treatment requests for AZEDRA®. (The "May Disclosures" by Dr. Anand.)**

118. **As Dr. Mahmood had feared, Progenics falsely reported to investors and the Securities and Exchange Commission that AZEDRA® had been successfully commercialized.**

119. For example, the May 9 Press Release quoted Progenics Chief Executive Officer Mark Baker, as follows:

120. "We are excited to report that the U.S. commercial launch of AZEDRA for the treatment of advanced or metastatic pheochromocytoma and paraganglioma is proceeding well and as expected."

121. The May 9 Press Release further states: "US Launch of AZEDRA® Progressing with 22 Treatment Requests from Patients Received and 12 Centers Throughout the U.S. are Ready to Treat Patients."

122. Further, the Progenics first quarter 10Q, filed on May 9, 2019 ("May 9 10Q"), includes the following statement:

> *AZEDRA® Launch*: A field-based team of Nuclear Medicine Technologists, Sales Representatives, Medical Science Liaisons and Access Specialists have been in the field since approval assisting centers of excellence and payers in the preparation for utilizing and reimbursing AZEDRA®. **As a result of this effort, treatment requests have been received and sites are now ready to administer AZEDRA®.**
>
> Progenics Form 10-Q, filed May 9, 2019 (*emphasis added*).

123. Based on his conversations with Dr. Anand and knowledge of the Violations, Dr. Mahmood believed, with good reason, that the statements regarding the marketing of AZEDRA® in both the May 9 Press Release and May 9 Form 10-Q, were untrue.

124. Specifically, Dr. Mahmood reasonably believed that, as he had expected, the Violations were intended to boost sales of off-label AZEDRA® to cover-up Progenics' failure to successfully market that drug.

125. The misrepresentations in both the May 9 Press Release and May 9 Form 10Q, Dr. Mahmood believed, reflected Progenics' continued efforts to fast-forward the sale of unapproved, off-label AZEDRA®, and thereby create sales reports that appeared, falsely, to confirm Progenics' statements to investors.

126. Further, on or about July 1, 2019 (the "July Disclosures"), Dr. Anand told Dr. Mahmood that a meeting among Progenics managers had been held on July 1, 2019 (the "July 1 Management Meeting"), attended by Dr. Das, CEO Mark Baker, Mr. Tenbarge, Patrick Fabbio, Progenics' Chief Financial Officer, and other Progenics executives.

127. The purpose of the July 1 Management Meeting, Dr. Anand told Dr. Mahmood, was to discuss AZEDRA®'s poor sales performance and the effect that such news might have on shareholders, potential investors, and the Velan Capital proxy challenge.

128. **Dr. Anand also told Dr. Mahmood that he had learned at the July 1 Management Meeting that only one patient outside the clinical trials had so far been treated with AZEDRA®. Dr. Anand further told Dr. Mahmood that the single patient that had been treated with AZEDRA® had soon died.**

129. Dr. Anand told Dr. Mahmood that the July 1 Management Meeting attendees - other than he - had agreed that sales for AZEDRA®, which totaled a mere $100,000, would not be broken out in Company's forthcoming l0Q.

130. Dr. Anand also told Dr. Mahmood that the other attendees had agreed to mask the weak sales of AZEDRA®, and the dearth of purchasers for on-label AZEDRA®, by including a single line item in the l0Q that would combine the drug's sales results with the proceeds of a separate, unrelated ~$5 million sales/licensing

agreement with Fuji Film.

131. Dr. Anand told Dr. Mahmood that he had learned at the July 1 Management Meeting that, despite Progenics' statements in a February 11, 2019 Press Release, Progenics' United States manufacturing facility – the Somerset Facility – did not have a sufficient long-term supply of iodine to produce AZEDRA® after August 2019.

132. Yet in the May 9 10Q, Progenics had made the exact opposite representation to shareholders, stating:

> *AZEDRA® Manufacturing.* In February 2019, we acquired the AZEDRA manufacturing assets for $8.0 million cash consideration and entered into a sublease agreement for the radiopharmaceutical manufacturing facility located in Somerset, New Jersey. The Somerset site serves as the launch facility for AZEDRA and will also provide manufacturing support for our development stage radiopharmaceuticals, including 1095. **We also secured the long-term supply of iodine necessary for the production of both AZEDRA and 1095 and entered into an agreement with a contract manufacturing organization for additional capacity and supply of iodine products**.
>
> Progenics Form 10-Q, filed May 9, 2019 (Emphasis added).

133. Based on these subsequent events, including the May Disclosures and July Disclosures, Dr. Mahmood was affirmed in his ongoing, reasonable concerns that that the Violations would lead to violation of the provisions of federal law relating to fraud, including wire fraud, bank fraud, and securities fraud. Securities Laws, including U.S.C.A. § 1341, and 17 C.F.R. § 240.10b-5.

134. Dr. Mahmood was aware, at all relevant times, that his whistleblowing was protected activity pursuant to the Sarbanes-Oxley Act, 18 U.S.C. § 1514.

135. On July 8, 2018, Dr. Mahmood filed a complaint against Progenics with the United States Department of Labor in accordance with 18 U.S.C. §

1514A(b)(l)(B), alleging illegal retaliation for whistleblowing.

136. On July 7, 2019, Dr. Mahmood filed a complaint with the Securities and Exchange Commission, in which he alleged the key facts regarding the improper marketing of AZEDRA®, and his illegal termination, set forth in this Complaint.

COUNT I
VIOLATION OF WHISTLEBLOWER
PROTECTION UNDER SARBANES-OXLEY, 15 U.S.C. § 1514A

137. Plaintiff repeats and realleges the allegations contained in paragraphs 1 through 136 of this Complaint as if fully set forth herein.

138. Progenics is a company within the meaning of 18 U.S.C. § 1514A.

139. Dr. Mahmood was an "employee" of Progenics protected by Sarbanes-Oxley 18 U.S.C.A. § 1514A(a).

140. The Sarbanes-Oxley Act, 18 U.S.C. § 1514A, provides protection against retaliation, including discharge, to employees of publicly traded companies who

> "...provide information, cause information to be provided, or otherwise assist in an investigation regarding any conduct which the employee reasonably believes constitutes a violation of section 1341, 1343, 1344, or 1348, any rule or regulation of the Securities and Exchange Commission, or any provision of Federal law relating to fraud against shareholders."

18 U.S.C. 1541A(a)(1)

141. An injured employee may seek relief by (A) filing a complaint with the Secretary of Labor; or (B) if the Secretary has not issued a final decision within 180 days of the filing of the complaint and there is no showing that such delay is due to the bad faith of the claimant, bringing an action at law or equity. *Id.*

142. Dr. Mahmood engaged in activity that was protected by Sarbanes

Oxley by, among other things, warning his Progenics supervisors and Progenics Management Team Members, Progenics Chief Medical Officer Dr. Asha Das and, through his direct report, Brian Dahl, Progenics Compliance Officer –about conduct that he reasonably believed violated federal law relating to fraud, including wire fraud, bank fraud, and securities fraud, including U.S.C.A. §1341 and 17 C.F.R. § 240.10b-5.

143. Dr. Mahmood reported his concerns to persons with supervisory authority over him, and to other supervisory persons working for or on behalf of his employer.

144. Dr. Mahmood's employment was terminated on April 18, 2019, one day after a written e-mail memorandum addressed to Dr. Das, his final act of whistleblowing.

145. Dr. Mahmood's protected activity was a contributing factor in Progenics' adverse employment action against him, which constituted discrimination against Dr, Mahmood in violation of Sarbanes-Oxley, 18 U.S.C. § 1514A.

146. As a result of Progenics' misconduct, including its improper termination of Dr. Mahmood's employment, Dr. Mahmood has suffered, and will continue to suffer, substantial damages, including but not limited to lost wages and benefits.

147. Progenics is liable to Dr. Mahmood for the damages he suffered because of its misconduct, including its termination of Dr. Mahmood in violation of Sarbanes-Oxley, 18 U.S.C. § 1514A.

148. As a result of Progenics' misconduct, including its improper termination of Dr. Mahmood's employment, Dr. Mahmood is entitled to compensation in the form of reinstatement, back pay, front pay in lieu of reinstatement, interest, attorneys'

fees and costs, and special damages, all in amounts to be determined at trial.

WHEREFORE, Plaintiff demands judgment against Defendant, as follows:

A. For violations of Sarbanes-Oxley, compensation in the form of reinstatement, back pay, front pay in lieu of reinstatement, interest, attorneys' fees and costs, and special damages, all in amounts to be determined at trial;

B. Such other and further relief as the Court deems just and proper.

Dated: Chappaqua, New York
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